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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019.676	04/08/2002	Sam Fong Yau Li	2577-118	7819
6449	7590	08/01/2006	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,676	LI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-91 and 94-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-91 and 94-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 73-91 and 94-100 are pending and under consideration.
2. In the prior action, the Final action mailed on November 1, 2005, claims 73-91 and 94-100 under consideration and rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 3, 2006 has been entered.

In the amendment, claims 73 and 95 have been amended.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(New Rejection)** Claims 73-91 and 94-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims were previously amended to include the

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claim language “wherein said contacting occurs without the need for a prior washing step following the negative test.” They have now been amended to read on methods “wherein said contacting occurs without a prior washing step following the negative test.”

To support these amendments, the Applicant points to disclosures on page 15 (lines 6-8) and pages 28-29 in the application. See, Response of September 2005, page 9. These portions of the application are drawn to the reusability of the described Pz crystals. However, both of these sections of the application are silent as to the use of a washing step. Further, with respect to the disclosure on page 28, it is noted that while the description on that page is silent as to the use of a wash, the reference does teach the incubation of the crystal to produce the indicated frequency changes. It is noted that this disclosure is part of the teachings of Example 2 in the application. On page 25, the application does teach the sample test protocol that was used in the disclosed methods. According to lines 24-26, the crystals are in fact washed after the tests are performed, but prior to determining the results therefore. In view of these teachings, and lack of any description in the application of the claimed method wherein the washing step is omitted, the claims are rejected as lacking written descriptive support for the presently claimed embodiments. I.e., the claims are rejected as comprising New Matter to the application.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **(Prior Rejection- Maintained in part)** Claims 73, 74, 76, 78-81, 83, 84, 90, 91, 95, 97, and 99-100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Thorns (U.S. Patent 5,510,241) and of U.S. Patent 5,306,644. The claims have been amended to require that the methods of claims 73, 74, 76, 78-81, 83, 84, 90, 91, 99, and 100; and the method in which the products of claims 95 and 97 is intended to be used; does not include a washing step after the performance of a negative test. In view of the amendment, in conjunction with the Applicant's arguments in traversal as supported by the declaration of Yap Him-Hoo, the rejection of the method claims is withdrawn.

However, with respect to claims 95 and 97, these claims are drawn to compositions comprising a Pz crystal comprising an electrode on which an antigen from an infectious agent associated with a veterinary disease, or an antibody to such an antigen, is immobilized. With respect to these inventions, the indicated method steps represent an intended use that does not affect the structure of the claimed PZ crystal. In such cases, the provision in the claims of an intended use does not distinguish the claimed product from a structurally identical product in the prior art. See e.g., MPEP 2114. In the present case, as was indicated in the prior actions, the teachings of the Bastiaans references teach a Pz crystal such as is presently claimed, and the teachings of the Bastiaans and Larue references teach a Pz crystal as described in claim 73 immunodiagnostics in general, and the teachings of the Thorns and the '644 patent illustrate, respectively, that it would have been obvious to those of ordinary skill in the art to adapt such devices for the detection of either *S. enteritidis* or for use in veterinary applications. Thus, the

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combined teaches of these references render the claimed compositions obvious regardless of the intended use provided in the claims. This rejection is therefore maintained against product claims 95 and 97.

8. **(Prior Rejection- Maintained in part)** Claims 73-76, 78-81, 83, 84, 90, 91, 95-97, 99 and 100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Rajashekara et al. (WO 98/03656). For the reasons indicated above, this rejection is withdrawn from the method claims 73-76, 78-81, 83, 84, 90, 91, 99, and 100; and is maintained against product claims 95-97.

9. **(Prior Rejections- Withdrawn)** Claims 77, and 85-89 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara, as these references were applied against the previous versions of the above claims, and of Willner et al. (WO 98/40739, Willner I- of record in the April 2002 IDS). Claim 82 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Willner et al. (WO 97/04314, Willner II- of record in the April 2002 IDS). For the reasons indicated above, these rejections are withdrawn from method claims 77, 82, and 85-89.

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10. **(Prior Rejection- Maintained in part)** Claims 94 and 98 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Masten et al., J Bacteriol 175: 5359-65 and in view of Protein Accession CAA78777. For the reasons indicated above, this rejection is withdrawn from the method claim 94; and is maintained against product claim 98.

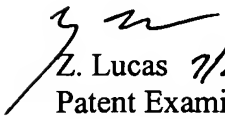
Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas 7/27/06
Patent Examiner